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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,336	11/26/2003	Reinhard Ebner	1488.0630003	3162

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STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
ROMEO, DAVID S	
ART UNIT	PAPER NUMBER
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	01/11/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/11/2007.

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fadkt@skgf.com

TH

Office Action Summary	Application No.	Applicant(s)	
	10/721,336	EBNER ET AL.	
	Examiner	Art Unit	
	David S. Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0204*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 10/13/2006 has been entered. Claims 24–39 are pending.

Applicant's election with traverse of the subject matter of Group I, directed to polynucleotides encoding SEQ ID NO:2, represented by original claims 1–13 and 18 (now canceled), and new claims 24 to 39 in the reply filed on 10/13/2006 is acknowledged. The traversal is on the ground(s) that claims directed to polypeptides, polynucleotides encoding such polypeptides, antibodies that specifically bind to such polypeptides, and methods of using the same should be searched and examined in the present application. This is not found persuasive because applicants' arguments are moot in view of applicants' cancellation of claims 1–23 and presentation of new claims 24–39 directed to subject matter falling within the ambit of Group I as cast by the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 24–39 are being examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33–39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in

the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

ATCC Deposit No. 97756 is essential to the claimed invention and must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the nucleic acid molecules are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the nucleic acid molecules. The specification does not disclose a repeatable process to obtain the nucleic acid molecules and it is not apparent if the nucleic acid molecules are readily available to the public. It is noted that Applicant has deposited the nucleic acid molecules, but there is no indication in the specification as to public availability. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific nucleic acid molecules have been deposited under the Budapest Treaty and that the nucleic acid molecules will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. § 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." If necessary, the specification should be amended to include the date of the deposit and the address of the depository. The address for the ATCC is:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

Claims 32 and 34–39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32 and 34–39 are directed to or encompass a polynucleotide encoding a "mature" form of a polypeptide. Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "mature" an artisan cannot determine what additional or material limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24–39 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The specification discloses a protein, connective tissue growth factor-3 (CTGF-3), having the amino acid sequence of SEQ ID NO:2 and discloses that the protein can be made by protein synthesis techniques well known in the art. There is no description of the chemical, physical, or biological properties for the protein other than the sequence. The specification does not disclose a specific biological role of CTGF-3 or its significance.

Although connective tissue growth factors belong to the CCN peptide family, most of the members of the CCN family lack a clear biological activity and the development of biological assays for these molecules is problematic. See Grotendorst (Cytokine Growth Factor Rev. 1997 Sep;8(3):171-9), page 172, paragraph bridging columns 1-2 and page 174, column 1, full paragraph 1. Grotendorst (published in 1997) teaches that progress in understanding the functions of the CNN family of peptides has been limited in spite of the cloning of cef/10 (identified in 1989), cyr61 (identified in 1990), Fisp12 (identified in 1991), and nov (identified in 1992) (page 174, column 2, full paragraph 1, and the references cited therein). It is noted that although CTGF, cef/10, cyr61, Fisp12, and nov belong to the same family of structurally related proteins, Grotendorst does not ascribe a biological role, function, or activity based on the structural relatedness.

The disclosed utilities associated with the claimed protein are based upon its homology with CTGF-1. CTGF-3 is about 44% identical and about 59% similar to human CTGF-1 (page

7, lines 27-30). Zhang (Mol Cell Biol. 1998 Oct;18(10):6131-41) discloses a protein, rCop-1, that is ~70% identical to SEQ ID NO: 2, as indicated below:

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  Query Match             70.6%;  Score 1019;  DB 11;  Length 250;
  Best Local Similarity   70.8%;  Pred. No. 1.3e-91;
  Matches  177;  Conservative   19;  Mismatches   54;  Indels    0;  Gaps    0;

Qy       1 MRGTPKTHLLAFSLLCLLSKVRTQLCPTPCTCPWPPPRCPLGVPLVLDGCGCCRVCARRL 60
           |||:|   ||| | ||||| |  ||| ||||||| ||:|| ||||||||||||:||||||
Db       1 MRGSPLIRLLATSFLCLLSMVCAQLCRTPCTCPWTPPQCPQGVPLVLDGCGCCKVCARRL 60

Qy      61 GEPCDQLHVCDASQGLVCQPGAGPGGRGALCLLAEDDSSCEVNGRLYREGETFQPHCSIR 120
            | |: ||||: |||||||||||||| ||:||| |||  |||||| | :||||:|:| :
Db      61 TESCEHLHVCEPSQGLVCQPGAGPGGHGAVCLLDEDDGDCEVNGRRYLDGETFKPNCRVL 120

Qy     121 CRCEDGGFTCVPLCSEDVRLPSWDCPHPRRVEVLGKCCPEWVCGQGGGLGTQPLPAQGPQ 180
           |||:|||||:||||||| ||||||| |:|::| |||||||| ||     |   ||| |
Db     121 CRCDDGGFTCLPLCSEDVTLPSWDCPRPKRIQVPGKCCPEWVCDQGVTPAIQRSAAQGHQ 180

Qy     181 FSGLVSSLPPGVPCPEWSTAWGPCSTTCGLGMATRVSNQNRFCRLETQRRLCLSRPCPPS 240
            | ||:      | | |||||||||||||||:||||||||||:|| |||||| |||  :
Db     181 LSALVTPASADAPWPNWSTAWGPCSTTCGLGIATRVSNQNRFCQLEIQRRLCLPRPCLAA 240

Qy     241 RGRSPQNSAF 250
           |  |  ||||
Db     241 RSHSSWNSAF 250.
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rCop-1 was identified by mRNA differential display as a gene whose expression became lost after cell transformation. Unlike the other members of the CCN gene family, rCop-1 is not an immediate-early gene, it lacks the conserved C-terminal domain which was shown to confer both growth-stimulating and heparin-binding activities, and its expression is lost in cells transformed by a variety of mechanisms. Ectopic expression of rCop-1 by retroviral gene transfers led to cell death in a transformation-specific manner. These results suggest that rCop-1 represents a new class of CCN family proteins that have functions opposing those of the previously identified members. See the Zhang's Abstract.

Furthermore, Henikoff (Science. 1997 Oct 24;278(5338):609-14) teaches that shared modules in proteins are to be used as guides for further research. Henikoff expresses uncertainty about gene classification (page 609, column 1, paragraph bridging columns 1-2) and family

relationships are complex (paragraph bridging pages 613-614); computer-based tools may not be the solution (page 614, column 1, full paragraph 1). It is noted that the instant specification fails to correlate a specific function of CTGF-3 with any given module of CTGF-3, or even with the entire protein.

Further experimentation is necessary to attribute a utility to the claimed protein. See Brenner v. Manson, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing", and stated in the context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful completion.").

Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. After further characterization the CTGF-3 polynucleotide, polypeptide and antibodies thereto may be found to have a patentable utility. This further characterization, however, is part of the act of invention, and until it has been undertaken the claimed invention is incomplete. In the absence of a knowledge of the biological significance of this protein, there is no immediately obvious patentable use for it. To employ the polynucleotides and polypeptides of the instant invention in order to raise antibodies, which antibodies are useful for detecting the polypeptide, for the diagnosis and prognosis of connective tissue related disorders, therapeutically, or for chromosome identification is clearly to use them as the object of further research which is a non-patentable utility. Furthermore, the specification lacks evidence supporting these utilities. Assertions that the CTGF-3 polypeptide or polynucleotide have utility for the above purposes requires sufficient support in the

application's disclosure. The patentability of CTGF-3 polypeptides and polynucleotides will require more that the mere allegation of utility.

Claims 24–39 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

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ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE HTTP://PAIR-DIRECT.USPTO.GOV. CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
JANUARY 3, 2007